PROFESSIONAL USE INFORMATION

LASER IN SITU KERATOMILEUSIS (LASIK)

NIDEK EC-5000
EXCIMER LASER SYSTEM

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Document Part Number: 16006-P882A
05.00

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CAUTION

Restricted Device:

U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

U.S. Federal Law restricts the use of this device to practitioners who have been trained in surgical treatment and management of the cornea or refractive errors, and in the operation, maintenance and calibration of this system.

This manual is supplied to provide information on the intended clinical use of the Nidek EC-5000 Excimer Laser System. For complete information concerning laser system components, laser safety, installation, maintenance, and troubleshooting refer to the NIDEK Excimer Laser Operator's Manual.

WARNING:

The user is responsible to read all instructions before use of this system. Pay attention to all warnings, contraindications, and precautions noted in these instructions, the Operator's Manual, and other related materials. Failure to do so may result in harm to a patient or user of the system.

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1. BRIEF DEVICE DESCRIPTION

The 193 nm Nidek EC-5000 Excimer Laser System is intended to perform keratectomy on exposed corneal tissue to modify corneal curvature for vision correction of both myopia and astigmatism. The Nidek EC-5000 laser performs optical correction by recontouring the exposed intrastromal surface of the cornea with a process referred to as photoablative decomposition. By controlling the shape and depth of the ablation, the EC-5000 changes the corneal curvature to correct refractive errors.

The excimer laser output is produced by electronically exciting a mixed molecular gas combination of argon and fluorine. This produces radiation in a far-ultraviolet wavelength which causes photodecomposition of molecular bonds. This process permanently removes tissue from the cornea without thermal injury to adjacent tissue structures.

2. INTENDED USE

The Nidek EC-5000 Excimer Laser System is intended for use in Laser in situ Keratomileusis (LASIK, also called Laser-assisted in situ Keratomileusis):

- treatments for the reduction or elimination of myopia with or without astigmatism ranging in severity from –1.00 to –14.00 D, in terms of manifest refraction spherical equivalent (MRSE), with refractive astigmatism ranging in severity from 0.00 D to –4.00 D cylinder by manifest refraction. Due to cylinder coupling effects on sphere, some combinations of cylinder and sphere are not possible in the lower range of the indications for use. A nomogram lookup table must be used for the entire refractive range for specific treatment combinations;
- patients who have a stable history of pretreatment myopia with or without astigmatism (i.e., a magnitude of change in manifest refraction of ≤ 0.50 D per year in terms of MRSE for at least one year preceding treatment);
- for myopic astigmatism, in patients who have a stable history of pretreatment astigmatism ≤ –4.00 D (i.e., a magnitude of change of ≤ 0.50 D per year in cylinder for at least one year preceding treatment); and
- patients who are over 21 years of age.

NOTE: You should be aware that the treatment ranges for PRK for myopia with and without astigmatism and LASIK are different. Please refer to the EC-5000 Operator's Manual, as needed, for specific treatment ranges.

3. CONTRAINDICATIONS

The Nidek EC-5000 Excimer Laser System should ***not*** be used to perform laser surgery:

- In patients who have a systemic disease that would influence corneal wound healing, particularly autoimmune or immunodeficiency diseases and collagen vascular diseases, including rheumatoid arthritis, systemic lupus, and Sjögren's syndrome.
- In patients who have current signs, early signs, or clinical indications of keratoconus.
- In patients who are pregnant or nursing.
- In patients with systemic conditions which would stimulate excessive scar tissue (keloid formation).
- In patients whose current medications include ocular or systemic steroid regimens that would affect their refractive correction.
- In patients who have irregular astigmatism as evidenced in topographical analysis.

4. WARNINGS

Laser Eye Surgery should ***not*** be performed on patients with an unstable refraction, (defined as a refractive change with a magnitude of > 0.50 D by MRSE per year or a refractive change with a magnitude of > 0.50 D in cylinder per year) since an under- or over-correction of treatment could result.

Laser surgery is ***not*** recommended for patients with a history of ocular *Herpes simplex* or ocular *Herpes zoster*. Reactivation of the virus may be a complication if these patients are treated with an excimer laser.

5. PRECAUTIONS

5.1. General

The safety and effectiveness of the Nidek EC-5000 Excimer Laser System has not been determined for use:

- In patients with active ocular disease, including but not limited to, uveitis, uncontrolled blepharitis, iritis, or severe dry eye.
- In patients with glaucoma and/or ocular hypertension (IOP >21 mm Hg).
- In patients who have insulin-dependent diabetes or clinically significant atopic disease.
- In patients currently taking medications which may affect corneal wound healing, including but not limited to, antimetabolites, retinoids, and sumatriptan succinate.
- In patients who have corneal epithelial, stromal, or endothelial dystrophy.

- In patients who have had previous penetrating ocular or corneal surgery.
- In patients who have previous corneal scarring in the treatment zone.
- In patients who demonstrate irregular astigmatism as seen in topographical analysis.
- In patients who have nystagmus or any other condition which would prevent a steady gaze during surgery.

The long term safety and effectiveness over 1 year follow-up has not been established.

5.2. Applicable to Patient Selection/Pre-Procedure

Caution should be exercised when selecting or treating patients with the Nidek EC-5000 Excimer Laser System based on the following criteria:

- A complete baseline ocular evaluation is essential, including cycloplegic evaluation (especially in older patients) to ensure that no opacities exist prior to treatment. Indirect ophthalmoscopy through a dilated pupil is required on myopic patients, for these patients tend to have a higher incidence of retinal pathology.
- Refractive stability must be demonstrated in patients. For this purpose, stability of refractive correction will be a magnitude change of ≤ 0.50 D in terms of MRSE, and a magnitude change of ≤ 0.50 D in cylinder, in the 12 month period preceding treatment. Contact lens wearers must refrain from wearing their soft contact lenses for at least two weeks, or hard lenses for three weeks. Stable refraction must be established at two examinations, one of which may be based upon documented refraction prescription history.
- Assessment of the optic nerves and intraocular pressures to screen for glaucoma must be performed prior to laser surgery. If patients demonstrate raised intraocular pressure or other signs of glaucoma, caution should be exercised when prescribing topical steroids post-operatively, or patients should not undergo laser refractive procedures.
- Pre-operative corneal topography is necessary on all patients to screen for potential topographical abnormalities. Corneal mapping may illustrate the presence of keratoconus or corneal warpage.
- Laser surgery is generally performed using a topical anaesthetic. Patients should be able to tolerate topical or local anesthesia.
- Patients should be able to lie in a supine position without difficulty.
- Patients should be able to demonstrate a steady gaze.
- Patients must be able to understand and give an informed consent for the surgery. All other alternatives to the correction, reduction, or potential elimination of their condition must be clearly communicated to patients.

- Patients who have higher pre-operative MRSE (i.e., attempted correction) and/or higher cylinder may have a higher chance of over- and under-correction (i.e., higher variability). Therefore, since patients tend to tolerate slight myopia better than slight hyperopia, a slightly myopic target outcome may be considered.

You should be aware that refractive laser procedures performed on eyes with pupils over 6 mm (at dim illumination) can experience varying degrees of problems with nighttime driving due to halos and/or glare.

For refractive errors above –14.00 D, there do not appear to be any new issues of safety or efficacy in this range of indicated refractive errors; however, the low number of patients in this category are not sufficient to detect actual complications and/or adverse event rates.

5.3. Applicable to Procedure

As with all laser output devices, the Nidek EC-5000 Excimer Laser System presents a potential hazard to patients and operators. Avoid inadvertent direct exposure of skin and eyes to the laser. Healthcare personnel who may approach the path of the primary beam should wear protective eyewear.

Confirm the data input for each procedure, so previously stored or default values are used only where indicated. If surgery is paused or terminated, the input parameter values remain in system memory for use or reference.

Before Laser Surgery:

- Care should be taken to plan the surgery so as to preserve a stromal bed thickness of at least 250 microns to reduce the risk of corneal ectasia secondary to LASIK.
- Prior to each treatment, carefully clean and assemble the microkeratome. Cleaning should be done between each procedure following the specific instructions and operator's manual provided by the microkeratome manufacturer. Only an experienced surgeon, nurse, or technician intimately familiar with the microkeratome should handle and prepare it.
- Inspect the blade under the microscope to detect nicks or irregularities. After the microkeratome has been reassembled, check the base plate thickness and the position of the translation stopper (if used). Test the microkeratome to verify that a smooth translation occurs in both directions.
- The use of any blowing gas on or across the cornea during laser treatment is not recommended.
- Verify the refractive astigmatism treatment axis (the steep axis) entered into the EC-5000 against the pre-operative topographic map.

Additional detailed procedures on the use of the EC-5000 excimer laser during the laser portion of LASIK treatment are described in the Operator's Manual.

Follow the procedures described in the manual to ensure safe and proper operation.

6. ADVERSE EVENTS

Table 6-1 summarizes the incidence of adverse effects reported in this study for all treated eyes (N=1126).

Table 6-1. Adverse Events

Adverse Event	1 month	3 months	6 months	12 months
Any corneal epithelial defect involving the keratectomy site at 1 month or later	0/1122 (0.0%)	1/1095 (0.1%)	0/938 (0.0%)	0/659 (0.0%)
Uncontrolled IOP with increase of >10 mm Hg above baseline	0/1122 (0.0%)	1/1095 (0.1%)	0/938 (0.0%)	0/659 (0.0%)
IOP reading above 25 mm Hg	0/1122 (0.0%)	2/1095 (0.1%)	0/938 (0.0%)	0/659 (0.0%)
Decrease in BsCVA* of >10 letters not due to irregular astigmatism (by hard contact lens refraction, at ≥ 6 months)			5/938 (0.5%)	3/659 (0.5%)

*BsCVA = Best spectacle corrected visual acuity

Other events that did not occur in this study that could occur following LASIK include: Corneal perforation; corneal infiltrate or ulcer; hyphema; hypopyon; post-treatment lens abnormalities with vision loss; persistent corneal decomposition/edema or cystoid macular edema; late onset of haze; lost, misplaced, or misaligned flap; melting of the flap; retinal detachment; and retinal vascular accidents.

Some adverse effects are reported every time they occur during the recovery period; others resolve themselves during the recovery period and are reported only if the condition persists post-operatively at 6 months or later.

For all treated eyes, the adverse effects that were reported only if present 6 months or more post-operatively included loss of more than 2 lines in best spectacle corrected visual acuity (0.7% at 6 months, 0.6% at 12 months), moderate or marked haze (0% at 6 months, 0.4% at 12 months), unintended induced astigmatism of greater than 2.00 D (0% at 6 and 12 months), over-correction > +2.00 D (1.2% at 6 and 12 months), and under-correction < –2.00 D (1.7% at 6 months, 0.6% at 12 months). The distribution of over- and under-correction at 6 months was slightly shifted to the left (i.e., under-correction greater than over-correction).

Table 6-2 below summarizes the incidence of complications reported in this study for all treated eyes (N=1126).

Table 6-2. Complications

Complications	7-30 days	1 month	3 months	6 months	12 months
Corneal edema between 1 week & 1 month after the procedure	0/1125 (0.0%)	0/1122 (0.0%)			
Peripheral corneal epithelial defect at 1 month or later		0/1122 (0.0%)	0/1095 (0.0%)	2/938 (0.2%)	0/659 (0.0%)
Epithelium in the interface		0/1122 (0.0%)	1/1095 (0.1%)	1/938 (0.1%)	1/659 (0.2%)
Foreign body sensation at one month or later		10/1122 (0.9%)	8/1095 (0.7%)	5/938 (0.5%)	0/659 (0.0%)
Pain at one month or later		3/1122 (0.3%)	4/1095 (0.4%)	0/938 (0.0%)	0/659 (0.0%)
Ghost or double images in the operative eye		23/1122 (2.0%)	21/1095 (1.9%)	12/938 (1.3%)	7/659 (1.1%)
Flap is not of the size and shape as initially intended or micro-keratome stopped in mid-cut		0/1122 (0.0%)	0/1095 (0.0%)	0/938 (0.0%)	0/659 (0.0%)
Decrease in BsCVA > 2 lines		12/962 (1.2%)	6/939 (0.6%)	5/752 (0.7%)	3/499 (0.6%)

An analysis to evaluate the chance of over- or under-correction was performed stratified by pre-operative MRSE. The strata were defined as follows: pre-operative MRSE ≤ –7.00 D and pre-operative MRSE > –7.00 D. Over-correction of more than +2.00 D at 6 months occurred in 0.2% (1/428) of eyes with a pre-operative MRSE ≤ –7.00 D and 2.4% (8/327) of eyes with a pre-operative MRSE > –7.00 D. Under-correction of more than –2.00 D at 6 months occurred in 0.5% (2/428) of eyes with a pre-operative MRSE ≤ –7.00 D and 3.4% (11/327) of eyes with a pre-operative MRSE > –7.00 D.

A subjective assessment of patient symptoms was completed using questionnaires. The following complications were reported from the patient questionnaires used in the study: an increase in fluctuation of vision (40.0% pre-operatively vs. 64.3% post-operatively); glare (35.7% pre-operatively vs. 35.7% post-operatively); and difficulty in night driving (26.2% pre-operatively vs. 69.0% post-operatively).

7. CLINICAL RESULTS

7.1. Introduction

Nidek Technologies, Inc. designed and implemented a clinical trial to assess the safety and efficacy of the EC-5000 Excimer Laser System for the correction of myopia with or without astigmatism using a LASIK technique. The study was an open, prospective, stratified, multi-center study conducted in two parts.

7.2. Patients Studied

A total of 622 patients had a primary eye or both eyes treated (N=1126 total eyes consisting of 622 primary eyes and 504 secondary eyes) at eight clinical centers.

7.3. Principal Effectiveness and Safety Results

The data presented in this manual was collected using a pre-operative change in manifest refraction of ≤ 1.00 D.

A total of 622 patients had a primary eye or both eyes treated (N=1126 total eyes consisting of 622 primary eyes and 504 secondary eyes) and were included for safety and efficacy analysis. Table 7-1 summarizes key safety and efficacy variables for all treated eyes.

Table 7-1. Key Safety and Efficacy Variable

Whole group not consistent Cohort

	1 month	3 months	6	
EFFICACY VARIABLES	**n/N (%)**	**n/N (%)**	**n.**	
UCVA 20/20 or better	441/970 (45.5%)	396/943 (42.0%)	3 (·	
UCVA 20/40 or better	800/970 (82.5%)	724/943 (76.8%)	640/758 (84.4%)	433/505 (85.7%)
Difference from Intended: MRSE ± 0.50 D	566/962 (58.8%)	530/944 (56.1%)	455/755 (60.3%)	321/512 (62.7%)
MRSE ± 1.00 D	771/962 (80.1%)	733/944 (77.6%)	643/755 (85.2%)	446/512 (87.1%)
MRSE ± 2.00 D	915/962 (95.1%)	882/944 (93.4%)	733/755 (97.1%)	503/512 (98.2%)
SAFETY VARIABLES				
BsCVA worse than 20/40	6/965 (0.6%)	1/943 (0.1%)	1/754 (0.1%)	0/500 (0.0%)
Loss of 2 lines BsCVA	8/962 (0.8%)	3/939 (0.3%)	6/752 (0.8%)	5/499 (1.0%)
Loss of >2 lines BsCVA	12/962 (1.2%)	6/939 (0.6%)	5/752 (0.7%)	3/499 (0.6%)
BsCVA worse than 20/25; 20/20 or better pre-op	13/962 (1.4%)	4/939 (0.4%)	5/752 (0.7%)	4/499 (0.8%)

7.3.1. Pre-Operative Characteristics

Pre-operative characteristics are described for 1126 treated eyes in Tables 7-2 and 7-3 below. For UCVA, 107 eyes had extremely poor VA, beyond the conventional Snellen scoring categories, that could be grouped with the 20/200 or worse category. Three eyes did not have a valid pre-operative UCVA value and nine eyes did not have a valid pre-operative BsCVA value.

Table 7-2. Pre-operative Uncorrected Distance Visual Acuity

Worse than 20/200		20/200 to 20/100		20/80 to 20/50		20/40 or better	
N/N	%	N/N	%	n/N	%	n/N	%
785/1123	69.9%	302/1123	26.9%	28/1123	2.5%	8/1123	0.7%

Table 7-3. Pre-operative Best Spectacle Corrected Visual Acuity

20/40 or worse		20/25 to 20/30		20/20 or better	
n/N	%	n/N	%	n/N	%
9/1117	0.8%	139/1117	12.4%	969/1117	86.8%

Cases were divided into two strata for the clinical analysis: pre-operative MRSE ≤ –7.00 D and pre-operative MRSE > –7.00 D. Table 7-4 presents the number and proportion of eyes stratified by pre-operative MRSE.

Table 7-4. Eyes Stratified by Pre-operative MRSE

Pre-operative MRSE ≤ –7.00 D		Pre-operative MRSE > –7.00 D	
n/N	%	n/N	%
614/1123	54.7%	509/1123	45.3%

7.3.2. Post-Operative Results

Efficacy Results

Efficacy data are presented for 1126 treated eyes. All treatment settings in the study utilized an adjustment nomogram to account for the effect of cylinder treatment on sphere. The necessary nomogram is provided separately. Table 7-5 presents a summary of efficacy results stratified by pre-operative MRSE (i.e., ≤ –7.00 D, > –7.00 D, etc.) at 6 months. This data is presented on initial treatment only (i.e., excluding retreatment procedures).

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Table 7-5. Summary of Key Efficacy Variables at 6 months Stratified by Pre-Operative MRSE

Efficacy Variables	MRSE ≤ −7.00 D n/N (%)	MRSE > −7.00 D n/N (%)
UCVA 20/20 or better	238/431 (55.2%)	121/327 (37.0%)
UCVA 20/40 or better	371/431 (86.1%)	269/327 (82.3%)
Difference from Intended: MRSE ± 0.50 D	300/428 (70.1%)	155/327 (47.4%)
MRSE ± 1.00 D	395/428 (92.3%)	248/327 (75.8%)
MRSE ± 2.00 D	425/428 (99.3%)	308/327 (94.2%)

Uncorrected Visual Acuity (UCVA)

At the point of stability (6 months after treatment), 84.4% (640/758) of patients tested at 20/40 or better; 77.2% (585/758) tested at 20/32 or better; 65.6% (497/758) tested at 20/25 or better; and 47.4% (359/758) of patients tested at 20/20 or better.

Accuracy Of Manifest Refraction (Predictability Of Outcome)

Table 7-6 summarizes the accuracy of manifest refraction in terms of difference from intended outcome for the combined consistent cohort. All treatment settings in the study utilized an adjustment nomogram to account for the effect of cylinder treatment on sphere. The necessary nomogram is provided separately.

Table 7-6. Accuracy of Manifest Refraction (Predictability of Outcome)

Difference from Intended Outcome	MRSE 1 month	MRSE 3 months	MRSE 6 months	MRSE 12 months
	n/N (%)	n/N (%)	n/N (%)	n/N (%)
± 0.50 D	566/962 (58.8%)	530/944 (56.1%)	455/755 (60.3%)	321/512 (62.7%)
± 1.00 D	771/962 (80.1%)	733/944 (77.6%)	643/755 (85.2%)	446/512 (87.1%)
± 2.00 D	915/962 (95.1%)	882/944 (93.4%)	733/755 (97.1%)	503/512 (98.2%)
> ± 2.00 D	47/962 (4.9%)	62/944 (6.6%)	22/755 (2.9%)	9/512 (1.8%)
Under-corrected < –2.00 D	31/962 (3.2%)	53/944 (5.6%)	13/755 (1.7%)	3/512 (0.6%)
Under-corrected < –1.00 D	136/962 (14.1%)	176/944 (18.6%)	78/755 (10.3%)	41/512 (8.0%)
Over-corrected > +1.00 D	55/962 (5.7%)	35/944 (3.7%)	34/755 (4.5%)	25/512 (4.9%)
Over-corrected > +2.00 D	16/962 (1.7%)	9/944 (1.0%)	9/755 (1.2%)	6/512 (1.2%)

Table 7-7 demonstrates the predictability of outcome for all treated eyes stratified by pre-operative MRSE of ≤ –7.00 D and > –7.00 D and at the point of stability (6 months) for pre-operative MRSE ≥-10.0 D.

Table 7-7. Accuracy of Manifest Refraction (Predictability of Outcome) Stratified by Pre-Operative MRSE

A: Pre-Operative MRSE ≤ –7.00 D

Difference from Intended Outcome	MRSE 1 month	MRSE 3 months	MRSE 6 months	MRSE 12 months
	n/N (%)	n/N (%)	n/N (%)	n/N (%)
± 0.50 D	350/519 (67.4%)	336/516 (65.1%)	300/428 (70.1%)	209/304 (68.8%)
± 1.00 D	447/519 (86.1%)	438/516 (84.9%)	395/428 (92.3%)	282/304 (92.8%)
± 2.00 D	514/519 (99.0%)	504/516 (97.7%)	425/428 (99.3%)	304/304 (100.0%)
> ± 2.00 D	5/519 (1.0%)	12/516 (2.3%)	3/428 (0.7%)	0/304 (0.0%)
Under-corrected < –2.00 D	3/519 (0.6%)	11/516 (2.1%)	2/428 (0.5%)	0/304 (0.0%)
Under-corrected < –1.00 D	55/519 (10.6%)	70/516 (13.6%)	27/428 (6.3%)	16/304 (5.3%)
Over-corrected > +1.00 D	17/519 (3.3%)	8/516 (1.6%)	6/428 (1.4%)	6/304 (2.0%)
Over-corrected > +2.00 D	2/519 (0.4%)	1/516 (0.2%)	1/428 (0.2%)	0/304 (0.0%)

B: Pre-Operative MRSE > –7.00 D

Difference from Intended Outcome	MRSE 1 month	MRSE 3 months	MRSE 6 months	MRSE 12 months
	n/N (%)	n/N (%)	n/N (%)	n/N (%)
± 0.50 D	215/441 (48.8%)	193/426 (45.3%)	155/327 (47.4%)	112/208 (53.8%)
± 1.00 D	323/441 (73.2%)	294/426 (69.0%)	248/327 (75.8%)	164/208 (78.8%)
± 2.00 D	400/441 (90.7%)	376/426 (88.3%)	308/327 (94.2%)	199/208 (95.7%)
> ± 2.00 D	41/441 (9.3%)	50/426 (11.7%)	19/327 (5.8%)	9/208 (4.3%)
Under-corrected < –2.00 D	27/441 (6.1%)	42/426 (9.9%)	11/327 (3.4%)	3/208 (1.4%)
Under-corrected < –1.00 D	80/441 (18.1%)	105/426 (24.6%)	51/327 (15.6%)	25/208 (12.0%)
Over-corrected > +1.00 D	38/441 (8.6%)	27/426 (6.3%)	28/327 (8.6%)	19/208 (9.1%)
Over-corrected > +2.00 D	14/441 (3.2%)	8/426 (1.9%)	8/327 (2.4%)	6/208 (2.9%)

C: Pre-Operative MRSE ≥-10.0 D at the Point of Stability (6 months)

Difference from Intended Outcome	-10.0 D to -11.99 D	-12.0 D to –13.99 D	≥-14.0 D
	n/N (%)	n/N (%)	n/N (%)
± 0.50 D	39/77 (50.6%)	3/20 (15.0%)	0/4 (0.0%)
± 1.00 D	58/77 (75.3%)	11/20 (55.0%)	0/4 (0.0%)
± 2.00 D	72/77 (93.5%)	16/20 (80.0%)	3/4 (75.0%)

The precision (accuracy of MRSE post-op to target for MRSE ±1.0 D) is significantly lower for refractive errors of ≥10.0 D of myopia.

Stability of Refractive Outcome

To determine this "point of stability" after treatment, refractive stability was evaluated between pairs of consecutive follow-up visits (i.e., 1 to 3 months, 3 to 6 months, etc.). The mean MRSE change from intended outcome across time provides a clear estimate of the point of stability as well as any significant regression trend. The data show that 96.4% of changes in MRSE are within ±1.00 D for all treated eyes for the 3 to 6 month time period, which is defined as the "point of stability." Table 7-8 reveals that >95% of all treated eyes fall within ±1.0 D MRSE of the previous evaluation, for each consecutive exam.

Table 7-8. Stability of Manifest Refraction After LASIK

All Treated Eyes

Period	Change in MRSE of ±1.00 [95% CI for %]	Mean Δ MRSE ± SD [95%CI for mean Δ]
3-6 Months	**644 / 668 (96.4%)** [95.0, 97.8]	**-0.05 ± 0.47** [-0.08, -0.01]
6-12 Months	**427 / 445 (96.0%)** [94.1, 97.8]	**-0.06 ± 0.49** [-0.11, -0.02]

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7.4. Summary of Key Safety Variables and Retreatment

Key safety variables include data collected on 1126 treated eyes. Table 7-9 presents a summary of the safety results stratified by pre-operative MRSE (i.e., pre-operative MRSE ≤ –7.00 D, pre-operative MRSE > –7.00 D) at 6 months.

Table 7-9. Summary of Key Safety Variables at 6 months Stratified by Pre-operative MRSE

Safety Variables	MRSE ≤ –7.00 D	MRSE > –7.00 D
	n/N (%)	n/N (%)
BsCVA worse than 20/40	1/431 (0.2%)	0/323 (0.0%)
Loss of 2 lines BsCVA	3/430 (0.7%)	3/322 (0.9%)
Loss of >2 lines BsCVA	2/430 (0.5%)	3/322 (0.9%)
BsCVA worse than 20/25; 20/20 or better pre-op	2/430 (0.5%)	3/322 (0.9%)

Refer to Tables 6-1 and 6-2 for a summary of the adverse events and complications that occurred in this study.

LASIK retreatment procedures with the EC-5000 Excimer Laser System were performed under the protocols on 197 eyes from the 1126 total patient eyes enrolled in the study. This reflects a retreatment rate of 17.5% (197/1126) for the overall study.

8. CONFORMANCE TO STANDARDS

The Nidek EC-5000 Excimer Laser System complies with internationally recognized JIST electrical standards.

9. HOW SUPPLIED

The base unit Nidek EC-5000 Excimer Laser System includes the laser generator, excimer laser, beam delivery, optical system for observation of the patient and the procedure, gas system, and computer system control. The System requires periodic maintenance and care, particularly for the gas system. Refer to the Operator's Manual for care instructions and precautions.

Options include a CCD color camera, TV camera adapter, color monitor, computer desk, foot controller (X,Y,Z adjustment), laser goggles, calibration unit and plates, cylinder stand (large, small), and buffer tube: 5m (for outside cylinder).

10. OPERATOR'S MANUAL

The Operator's Manual (Document Part Number: 16006-P912G) is supplied separately.

11. LASIK NOMOGRAM LOOKUP TABLE

The LASIK Nomogram Lookup Table with the accompanying Information for Use instruction sheet (Document Part Number: 16006-P892A) is supplied separately. The Nomogram Lookup Table restricts treatment combinations to the following limits:

For Sphere Treatments of (D)	Upper Limit of Cylinder Treatment (D)
–0.75	–1.00
–1.00	–1.25
–1.25	–1.50
–1.50	–1.75
–1.75	–2.00
–2.00	–2.25
–2.25	–2.50

For Sphere Treatments of (D)	Upper Limit of Cylinder Treatment (D)
–2.50	–2.75
–2.75	–3.00
–3.00	–3.25
–3.25	–3.50
–3.50	–3.75
≥–3.75	–4.00

PATIENT INFORMATION BOOKLET

Photorefractive Surgery Performed as an Intrastromal Keratectomy under a Keratomileusis Flap (LASIK) for Myopia (Nearsightedness) and Astigmatism

Nidek EC-5000 Excimer Laser System

SURGICAL LASER TREATMENT FOR NEARSIGHTED PATIENTS WITH VISION CORRECTION –1.00* TO –14.00 DIOPTERS SPHERICAL EQUIVALENT AND HAVING ASTIGMATISM 0.00 TO –4.00 DIOPTERS OF CYLINDER

* Ask your doctor about certain limitations in the lower range of correction. You may not be qualified for treatment with certain amounts of astigmatism.

Please read this entire booklet. Discuss its contents with your doctor so that all of your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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Document Part Number: 16006-P872A 05.00

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1. Introduction

Please read the following information if you are thinking about having a type of laser surgery, called Laser in situ Keratomileusis[1] (LASIK, also called laser-assisted in situ keratomileusis), performed to correct nearsightedness (myopia) with or without treatment for astigmatism. The options for correction of myopia and astigmatism now include glasses, contact lenses, and different kinds of refractive surgery such as radial keratotomy (RK), automated lamellar keratoplasty, surface treatment by photorefractive keratectomy (PRK), and LASIK using excimer lasers, including the Nidek EC-5000 Excimer Laser System.

This information can help you make an informed decision when selecting a method to correct your nearsightedness. If both of your eyes are nearsighted, your doctor may recommend LASIK surgery for both eyes to achieve satisfactory vision. However, there are cases where it is better to reshape the cornea on only one eye. For example, one reason for treating only one eye is that you may use the eye for looking close up and one eye for looking far away.

Please read this booklet completely. Discuss any questions you may have with your doctor in order to decide if LASIK is the right choice for you. Only a trained and certified practitioner can determine whether or not you are a suitable candidate for LASIK. You should be aware that a small percentage of patients treated with excimer lasers experience permanent vision reduction. The goal of LASIK is to reduce your need for glasses or contact lenses by changing the shape of the cornea through LASIK laser surgery.

2. How the Eye Functions

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light

[1] Underlined terms are contained in the Glossary.

first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Normally, in relatively young persons (i.e., less than 50 years of age) the lens of the eye can adjust its focusing power somewhat, so you can see objects clearly both near and far away.

The eye focuses light by refracting all light rays to meet at a single point. If the focusing process works perfectly, a sharp image of the object you are looking at will be focused exactly on the retina and you will see a clear image. However, if the light focuses either in front of or behind the retina, the image on the retina (and the image you see) will be blurred, and you are said to have a refractive error. Refractive errors are not diseases, but are common variations observed in human beings across the world.

There are three main types of refractive error. They are called nearsightedness (myopia), farsightedness (hyperopia) and astigmatism. The amount of refractive error present in the eye is measured in units called "diopters." When your eye cannot focus correctly, it is said to have one of the main refractive errors: myopia or hyperopia.

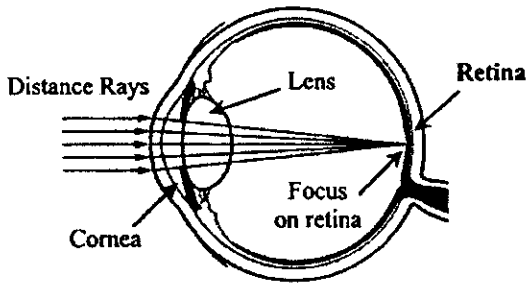
Myopia usually starts in childhood and typically stabilizes in the late teens or early adulthood. The tendency to develop myopia also runs in families. Myopia can range from a very mild to a very strong nearsighted effect. The range of treatment with the Nidek EC-5000 covers a large part of that range.

Hyperopia is also very common, and is especially problematic in older persons who have difficulty in focusing on objects up close. Currently, the Nidek EC-5000 is not approved for treating hyperopia.

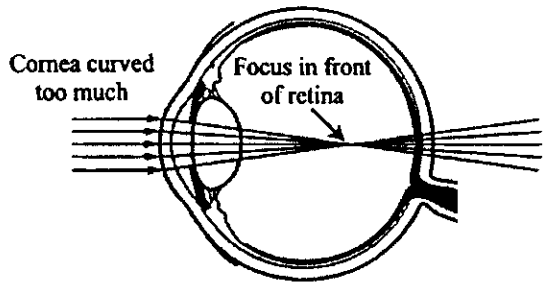
Astigmatism occurs when the refractive error is stronger in a particular direction. Astigmatism may occur with either myopia or hyperopia.

The following pictures emphasize the role of the cornea in determining the focusing power of the eye. They show that the more sharply the cornea is curved, the more the light rays are bent. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. When the cornea shape is just right, the image from a distant object is focused exactly on the retina. This proper focus for distance vision is called emmetropia.

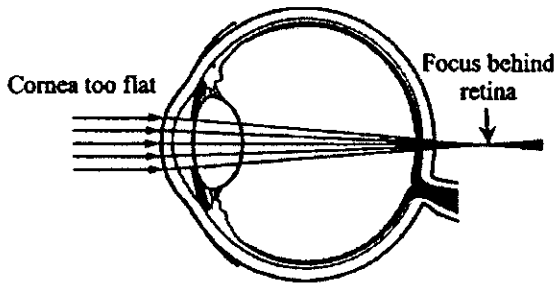
PROPER FOCUS



NEARSIGHTED EYE



FARSIGHTED EYE



Good focus depends on three factors, the overall shape and size of your eye, the shape of the cornea, and your lens power. During a regular eye examination, your doctor checks your vision to determine where the eye focuses light relative to your retina. When your doctor adjusts your vision with different lenses, he correctly focuses light on the retina.

Myopia affects about 25% of the population in North America. Myopic individuals see near objects clearly, but distant objects are blurry. Nearsightedness and astigmatism can be corrected by any method that reduces the total refractive power of the eye, and includes the use of glasses, contact lenses and refractive surgery. With glasses or contacts, changes in your vision that occur slowly over time can be corrected by simply adjusting the lens prescription of your glasses or contacts. Refractive surgery, on the other hand, produces changes that are permanent and cannot be undone or easily modified if your vision changes or if the initial surgery is not successful (2.9% of initial surgeries were found to be greater than 2.0 D from intended correction at 6 months after surgery).

3. What is LASIK?

LASIK is laser surgery to correct near-sightedness (myopia) with or without astigmatism. An excimer laser beam is used to flatten the middle layer of the cornea. The laser beam removes microscopic amounts of tissue from the middle layer of the cornea, precisely reshaping the cornea.

The excimer laser produces a beam of ultraviolet light in a series of rapid pulses. Each pulse lasts only a few billionths of a second and removes a microscopic amount of tissue by evaporating it. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, and retina) undisturbed. The laser produces very little

heat and is controlled by the doctor during the operation.

Prior to LASIK, some anesthetic drops are placed on the eye to numb it. Your doctor then begins the LASIK procedure by cutting a thin flap on the front of the cornea using a special cutting instrument called a micro-keratome. The doctor will then fold back this flap of tissue much like opening a hinged cabinet door. Folding back the flap will give the doctor access to the middle layer of the cornea where the laser treatment will be performed. This part of the procedure usually takes a couple of minutes. After that, your doctor uses the laser beam to perform the LASIK procedure. The laser treatment usually lasts only about 15-40 seconds. After the laser treatment is complete, the doctor will carefully fold the flap of cornea tissue back into place to complete the procedure.

This procedure is performed on one eye at a time even if both are to be treated. If all goes well with the first eye, and your vision stabilizes without complication or adverse reaction, then the second eye can be treated later. LASIK laser surgery on the second eye is usually done at least one week after the first eye, if needed.

4. Contraindications

You should not have LASIK surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS). These conditions may result in scarring or poor healing after LASIK treatment resulting in reduced vision.
- You are pregnant or nursing. These conditions may affect your preoperative refraction making it difficult to choose the correct amount of LASIK treatment.

- You show signs of thinning of the cornea (keratoconus) or corneal disease. This condition can lead to serious cornea problems that require additional surgical repair and result in poor vision.
- You have a condition which would stimulate large amounts of scar tissue (keloid formation). Scarring can be permanent and may require surgery to repair.
- You are taking prescription medications that affect corneal healing or your refraction. You should discuss all medications you take, even over-the-counter medications, with your eye doctor. Many medications can affect the way your cornea is changed by the laser and the way it heals after LASIK treatment. These may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.

5. Warnings

Discuss with your doctor if:

- Your nearsightedness is changing. If your vision is unstable, then you should not be treated. Treatment of unstable vision may affect the accuracy of your refractive results.
- You have severe allergies. Your medications may have to change before or after your eye surgery. These medications may change the wetness (moisture level) in your eye. If the medication changes the wetness of your eye, the accuracy of your refractive results may be affected.
- You have been diagnosed with ocular *Herpes simplex* or ocular *Herpes zoster*. Herpes are viral

infections. Laser treatment may reactivate the infection.

- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze. You need to be able to keep your eyes still during treatment. The accuracy of your refractive results will be affected if you can not keep your eyes still during treatment.

6. Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser has ***NOT*** been evaluated in patients with the following conditions or situations. Therefore, no statement regarding the safety and effectiveness can be made about the effect these situations may have on LASIK refractive surgery with the EC-5000:

- Eyes with disease or corneal abnormality.
- Eyes with previous surgery or injury to the center of the cornea where LASIK will be performed.
- Patients with glaucoma or high pressure in the eye.
- Patients taking insulin for diabetes.
- Patients over the long term (more than 1 year after the surgery).
- Patients under 21 years of age.

7. Risks

LASIK is a laser surgical procedure involving your eyes and has potentially serious risks. You should consider and discuss with your doctor the risks that are noted in this booklet. These are based on clinical experience with LASIK cases and the possible concerns that doctors believe should be considered for this kind of eye surgery.

See the information listed below for details on risks of complications and adverse events.

- ☐ At the time of surgery, it is possible that the flap will not be cut correctly. In some cases, the flap of tissue may not be the correct size or shape or may be too thin (0% of cases). In these cases, the doctor may have to stop the surgery, fold the flap into position, and allow it to heal. In most cases, the doctor can complete surgery at a later date. In the studies on LASIK, the majority of these cases were completed later and had a successful result.
- ☐ Although the effects of LASIK on visual performance under poor lighting conditions have not been determined, it is possible that you will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. These effects have been reported as being more common in persons with large pupils (over 6 mm). It is possible that these may be permanent effects.
- ☐ **The first week following surgery:**

  The following complications have been reported up to several weeks following LASIK treatment. They are associated with the normal healing process after treatment and include:

  - Discomfort (including mild to moderate pain, pressure, scratchiness, burning sensation, and dryness) may last for up to 1 day after surgery, for which your eye doctor can provide medications.
  - The feeling that something is in your eye.
  - Swelling of the cornea.
  - A problem with healing of the corneal flap, including damage to the flap, loss or misalignment of the flap,

or growth of cornea surface cells under the flap. If needed, the doctor may lift the flap to clean the μιδδλε layer of the cornea and reposition the flap to improve healing.

- Blurred vision and tearing or watery eyes may occur as the cornea and the flap heal.
- Sensitivity to bright lights.

❒ **The first one to six months following surgery:**

- Your intraocular pressure may increase due to use of steroid or anti-inflammatory medications (0% to 0.1% of eyes had a significant elevation in intraocular pressure in this time frame). This is usually resolved by drug therapy or by stopping the use of the steroid or anti-inflammatory medication.
- Hazy or cloudy vision rarely occurs after LASIK surgery (<1% of eyes had mild or moderate haze with no significant loss of vision).
- An increase in fluctuation of vision (40.0% pre-operatively vs. 64.3% post-operatively).
- Glare (35.7% pre-operatively vs. 35.7% post-operatively).
- Difficulty in night driving (26.2% pre-operatively vs. 69.0% post-operatively).

Caution: You should contact your doctor if you notice any pain or change or loss of vision in the eye. Eye pain or sudden loss of vision can indicate a serious problem that requries immediate medical attention.

❒ **One year after surgery:**

Nidek clinical studies showed that at one year after LASIK surgery the following vision-threatening events happened:

- Too large a correction (causing farsightedness more than +2.0 D) (1.2%).
- Losing a significant amount (more than 2 lines lost on an eye chart) of vision even with glasses (0.6%).

If the results of the surgery are not satisfactory, you may need to have additional LASIK surgery in the same eye.

8. Benefits

❒ LASIK surgery, as performed with the Nidek EC-5000 Excimer Laser, is effective in reducing nearsightedness requiring correction from –1.00 to –14.00 diopters spherical equivalent in patients with 0.00 to –4.00 diopters of astigmatism (85.2% of treated eyes were within 1.0 diopter of intended correction at 6 months).

❒ LASIK may reduce overall nearsightedness (84.4% significantly improved uncorrected vision to the level of 20/40 or better at 6 months).

❒ LASIK may reduce or eliminate dependency upon contact lenses or glasses (47.4% could see 20/20 or better without glasses or contacts at 6 months).

❒ LASIK should be considered a permanent surgical procedure, in that the refractive result changes little after the first few months. If your refractive result is unsatisfactory, your doctor may recommend further surgical treatments, or correcting your remaining refractive error with glasses or contacts.

9. Are You a Good Candidate for LASIK?

If you are considering LASIK, you must:

- Be at least 21 years of age.
- Have healthy eyes which are free from eye disease or corneal

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abnormality (for example: scar, infection, etc.).

- Have nearsightedness (myopia) requiring vision correction between –1.00 and –14.00 diopters spherical equivalent, with 0.00 to –4.00 diopters of astigmatism.
- Be sure your eye doctor has satisfactory evidence that your refraction has been stable over the past year (changed by ≤ 0.5 diopters in your vision correction, or by ≤ 0.5 diopters in your astigmatism correction).
- Be informed of LASIK risks and benefits as compared to other available treatments for nearsightedness (myopia) and astigmatism.
- Be willing to sign an informed consent form, as provided by your eye care professional.

Why LASIK may not be right for you:

- *If you expect perfect results.* No surgical procedure can assure you perfect results or can guarantee that your expectations will be met.
- *If you expect perfect vision under all conditions.* At night, eyes that have been reshaped by refractive procedures such as LASIK may experience glare and a variety of visual effects. The LASIK procedure only reshapes the central portion of the cornea and does not reshape the entire cornea. As a result, when the pupil of the eye dilates (over 6 mm) under low light conditions, it may open past the boundaries of the treated area producing unwanted changes in vision, such as halos and hypersensitivity to light. You may find that you will need to wear corrective lenses to drive at night.

LASIK treatment is not intended to eliminate the need for reading glasses. In some patients, reading glasses may be required after treatment even if they were not worn before treatment. As patients get to age 40 and beyond, they are more and more likely to require reading glasses when their distance vision is otherwise excellent. Nearly all older patients require reading glasses if their distance vision is fully corrected.

If the thought of occasionally wearing eye wear is uncomfortable, then LASIK may not be right for you.

- *If you expect an instant change in vision.* The visual results are not instant, even for patients with less than 4 diopters of correction. It may take up to 3 months, sometimes longer, for the shape of the cornea to stabilize following surgery. You must be patient and be willing to wait until the healing process finishes. You may also be asked to temporarily wear corrective lenses.

  Please note that various occupations may have certain restrictions regarding refractive surgery. Therefore, you should check with the appropriate people before having refractive surgery.

10. Before the Surgery

If you are interested in having LASIK, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for LASIK. This will include a complete eye history, and a thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

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WARNING

If you wear contact lenses, it is very important to stop wearing them 2-4 weeks before the evaluation. Failure to do this can affect the quality of your vision and the accuracy of your refractive result.

Before the surgery, please tell your doctor well in advance if you take any medications or have any allergies. Also, talk with your doctor about whether you can eat or drink immediately before the surgery. You should arrange for transportation for the day of surgery and your next doctor's appointment, since you must not drive immediately after the surgery. You can resume driving only after receiving permission from your doctor.

11. The Day of Surgery

Before the surgery, numbing (anesthetic) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during surgery. For protection and comfort, a temporary shield will cover the eye not having surgery.

- Your doctor may perform a brief practice treatment so you can hear and smell what the laser will be like during the treatment.
- Your doctor begins the procedure by using a cutting instrument, called a microkeratome, to cut a thin flap in the front of the cornea. The instrument used to hold your eyelids open may need to be changed between this part of the surgery and before doing the laser treatment.

- Next, the doctor repositions your head in the chair, and then carefully folds back the flap of tissue much like opening a hinged cabinet door. This gives the doctor access to the middle layer of the cornea where the laser treatment will be performed. The doctor then refocuses the microscope on your cornea. You will be asked to look directly at a blinking light. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. As you continue to look at the blinking light, small amounts of tissue will be removed from your cornea using the Nidek EC-5000 Excimer Laser.

PRECAUTION

It is very important that you keep looking at the blinking light during the procedure, even if the light fades or becomes dim. The quality of vision and accuracy of your refractive result after LASIK can depend upon you looking straight at this blinking light throughout the treatment.

- You will be exposed to laser energy for less than 1 minute. However, the entire surgical procedure takes about 10 to 15 minutes.
- After the laser surgery is complete, the doctor will fold the flap of cornea tissue back into place and gently smooth the surface. Some drops or ointment will be placed into your eye. Then it will be covered and patched for your protection and comfort. The surgery itself is painless because of the numbing actions of the anesthetic drops that were applied to your eye at the beginning of the procedure.

- After 45 to 60 minutes, the anesthetic will wear off and your eye may hurt for 1 to 3 days. Most patients describe this pain as moderate to severe. Do *NOT* rub your eyes for the first 3 to 5 days. Rubbing your eyes can damage the cornea and will delay healing. Your doctor can prescribe pain medication to make you more comfortable during the first week after the surgery.

WARNING

Your doctor will monitor you for any side-effects if topical steroids were used. The possible side-effects from prolonged use of topical steroids are an increase of pressure in the eye (ocular hypertension), glaucoma or cataract formation.

12. The First Days After Surgery

In your doctor's office, your eye patch will be removed the following day. You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

- Your vision should become stable within the first several weeks after surgery. Some patients may experience some small changes (for example, improvement or worsening of their vision). These changes may occur up to six months or more after surgery.
- Hazy or cloudy vision rarely occurs after LASIK surgery (<1% of eyes had mild or moderate haze).

IMPORTANT

Use anti-inflammatory eye drops and lubricants as directed by your doctor. The quality of your vision and the accuracy of your refractive result can depend upon you following your doctor's directions.

13. Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if LASIK is right for you:

- What other options are available for correcting my nearsightedness and astigmatism?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of nearsightedness and astigmatism?
- What quality of vision can I expect in the first few months after surgery?
- If LASIK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after LASIK if I need them?
- How is LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Is it likely I will need reading glasses sooner than later?
- Will my cornea heal differently if injured after having LASIK?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery on my other eye?

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- What vision problems might I experience if I have LASIK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser treatment is not covered by most health insurance policies.

14. Self-Test

Are you an informed and educated patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser refractive surgery is risk free.	[ ]	[ ]
2. Excimer laser surgery uses pulses of invisible light.	[ ]	[ ]
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	[ ]	[ ]
4. The laser does all the work; I just have to lie on the chair and close my eyes.	[ ]	[ ]
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	[ ]	[ ]
6. I may need reading glasses after laser surgery.	[ ]	[ ]
7. There is a risk that I may lose some vision after laser surgery.	[ ]	[ ]
8. It doesn't matter if I am pregnant.	[ ]	[ ]
9. If I have an auto-immune disease, I am still a good candidate for LASIK.	[ ]	[ ]

Answers to SELF-TEST are found at the top of page 20.

15. Summary of Important Information

- ☐ LASIK is a permanent operation to the cornea that cannot be easily changed.
- ☐ Alternatives to LASIK include glasses, contact lenses, RK, and PRK.
- ☐ LASIK is not a laser version of radial keratotomy (RK); they are completely different from one another.
- ☐ Some occupations, such as pilots, do not accept applicants who have had any refractive surgery.
- ☐ Refractive error must be stable (within ± 0.5 diopters in your vision correction, or within ± 0.5 diopters in your astigmatism correction) for at least one year before surgery.
- ☐ The following risks of LASIK surgery should be noted:
  - temporary discomfort may be expected for 24 to 72 hours after surgery. If the discomfort persists, please contact your doctor.
  - problems that may last several weeks: corneal swelling, blurred vision, feeling something in the eye, shadow images, light sensitivity, tearing, and pupil enlargement.
  - adverse events beyond the first few months: elevation of intraocular pressure (0% at 6 months); cloudy cornea affecting vision (0% at 6 months); over-correction by more than 2.0 diopters (1.2% at 6 months, 1.2% at 12 months); under-correction or nearsighted by more than 2.0 diopters (1.7% at 6 months, 0.6% at 12 months); loss of best vision that can be achieved with glasses (0.1% at 6 months); lost or damaged corneal flap (0% at 6 months); and ghost images (1.3% at 6 months).

- ❒ The following benefits of LASIK surgery should be noted:
  - Nearsightedness with astigmatism may be reduced so that the amount of time contact lenses or glasses are used during the day is reduced or eliminated.
  - LASIK may be an alternative to glasses in some patients who are intolerant of contact lenses.
  - LASIK may be another alternative to correct nearsightedness and astigmatism.
- ❒ Patients considering LASIK surgery should:
  - Discuss fully with one or more ophthalmic surgeons the complications of LASIK surgery, the risks and the time required for healing, and have a complete eye examination before making a final decision.
  - Read both the Patient Information Booklet and the Informed Consent Document (ICD) provided by your doctor carefully before signing the ICD.

Answers to Self-Test Questions:

1. False (see Risks on page 7);
2. True (see What is LASIK? on page 4);
3. False (see Before The Surgery on page 12);
4. False (see The Day of Surgery on page 13);
5. True (see Benefits on page 10);
6. True (see Why LASIK may not be right for you on page 11);
7. True (see Risks on page 7);
8. False (see Contraindications on page 5);
9. False (see Contraindications on page 5).

16. Summary Tables

Summary of Key Safety and Efficacy Variables at 6 months after Surgery	
Efficacy Variables	
Visual acuity without glasses or contacts:	
20/20 or better	47.4%
20/40 or better	84.4%
Treated eyes within range of target correction (MRSE):	
±0.50 diopters	60.3%
±1.00 diopters	85.2%
±2.00 diopters	97.1%
Safety Variables	
Visual acuity with glasses being 20/40 or worse	0.1%
Loss of more than 2 lines on vision chart with glasses on	0.7%
Visual acuity with glasses on worse than 20/25 when it was better than 20/20 before surgery	0.7%

At the point of stability (6 months), the precision (accuracy of MRSE post-op to target for MRSE ±1.00 D) is significantly lower for refractive errors of ≥10.0 D of myopia (see following table).

Pre-Operative MRSE ≥10.0 D at the Point of Stability (6 months)			
Difference from Intended Outcome	**-10.0 D to -11.99 D n/N (%)**	**-12.0 D to -13.99 D n/N (%)**	**≥14.0 D n/N (%)**
±0.50 diopters	39/77 (50.6%)	3/20 (15.0%)	0/4 (0.0%)
±1.00 diopters	58/77 (75.3%)	11/20 (55.0%)	0/4 (0.0%)
±2.00 diopters	72/77 (93.5%)	16/20 (80.0%)	3/4 (75.0%)

Complications and Adverse Events		
Description	Immediate Post-op to 1 Month	At 6 Months
Complications—		
Discomfort	----	0.0%
Haze (mild to moderate)	0.0%	0.0%
Foreign body sensation	----	0.5%
Ghost/double images	----	1.3%
Corneal swelling	0.0%	----
Peripheral corneal surface defect	----	0.2%
Flap not size and shape intended or not cut completely	----	0.0%
Adverse events—		
Corneal infiltrate or ulcer	----	0.0%
Lost or misaligned flap	----	0.0%
Elevated intraocular pressure (relative or absolute)	----	0.0%
Loss of visual acuity after 6 months	----	0.5%
Late onset haze with decreased vision	----	0.0%
Retinal accidents/detach.	----	0.0%

17. Glossary

Astigmatism—a refractive error that is stronger in one direction than others, usually corrected by glasses or contacts with a slight cylinder shape.

Automated lamellar keratoplasty—an older surgical technique to remove a thin layer of the cornea and reshape it to correct refractive error.

Collagen vascular disease—any of several conditions that alter the way your body creates and metabolizes normal connective tissue like collagen. The cornea is made mostly of collagen. Some common examples include lupus, scleroderma, and rheumatoid arthritis.

Corneal edema—a swelling of the cornea, common in response to eye surgery or injury, that sometimes causes temporary clouding of the cornea.

Corneal infiltrate—an infection or inflammatory response that penetrates into the cornea, often more difficult to treat than a surface problem.

Cylinder—describes the barrel shaped lens required to fix your astigmatic refractive error.

Efficacy—how well or effectively a treatment performs.

Increase in fluctuation of vision—variations in vision more than usual or normal that are easily noticed by a person when lighting conditions change (e.g., daytime compared to nighttime vision).

Intraocular pressure (IOP)—the normally constant fluid pressure inside the eye. When too high, it can cause glaucoma.

Laser in situ keratomileusis (LASIK)—use of an excimer laser to treat refractive error under a thin flap of the cornea. The flap is made first, moved out of the way for laser treatment, then replaced to cover the treatment area.

MRSE—the manifest refraction spherical equivalent, a measure of the overall lens power of the refractive correction needed by your eye.

Radial keratotomy (RK)—a surgical treatment to correct refractive error using small cuts to change the shape of the cornea.

Recurrent erosions—a repeated uncovering of the corneal epithelial cells that protect the cornea.

Refractive surgery—surgery to change how the eye focuses to correct refractive error. This includes the use of laser surgery or cuts to alter the shape of the cornea, implantation of small lenses or rings, or surgical removal of a clear lens.

Sphere—describes the round shaped lens required to fix your refractive error when you do not have astigmatism.

INFORMATION CENTER

Primary Eye Care Professional

[This information can be pre-printed by physician offices]

Name:

Address:

Phone:

Doctor Performing LASIK

Name:

Address:

Phone:

Treatment Location

Name:

Address:

Phone:

Laser Manufacturer:

Nidek Co., Ltd.
Gamagori, Japan

U.S.A. Offices:

Nidek Incorporated
47651 Westinghouse Drive
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